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| 10/809,654 | 03/25/2004 | Zhonglin Hao | 00497-08 | 8532 |

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UNIVERSITY OF VIRGINIA PATENT FOUNDATION
250 WEST MAIN STREET, SUITE 300
CHARLOTTESVILLE, VA 22902

EXAMINER

CHISM, BILLY D

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/809,654

Applicant(s)

HAO ET AL.

Examiner

B. Dell Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19, 20 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 20 and 29 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/21/04 - 5-19-04</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This office action is in response to Applicants' papers filed 06 December 2005. Claims 19-20 and 29 are pending.

Withdrawal of Objections and Rejections

2. The rejections and/or objections made in the prior office action 2 June 2005, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 6 December 2005 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Objections

3. (New) Claim 20 is objected to because of the following informalities: the claim 1 contains to identifiers to begin the sentence, i.e. "A" and "The", wherein the claim should begin with only "The". Additionally, the claim 1 has two transitional terms, i.e. "comprises" and "comprising", wherein, the claim should only have "comprises". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. (New) Claims 19-20 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains,

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or with which it is most nearly connected, to make and/or use the invention. In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988) as to undue experimentation. Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation. The factors follow:

1. the nature of the invention;

The claims are drawn to C58 protein sequence with antigenic properties.

2. the breadth of the claims;

There is a myriad of possible amino acid sequence available including, multiple substitutions of one to twenty conservative substitutions along the entire length of the C58 peptide, to single mutations, i.e. deletion, insertion or substitution. Additionally, there can be any sequence as long as the sequence comprises C58 sequence.

3. the predictability or unpredictability of the art;

The prior art is limited in the claimed area of invention. The prior art does not teach instantly claimed C58 peptide. The prior art is limited with regard to results for sperm-specific peptides used in vaccine contraceptive processes. In fact, O'Hern et al. (Biology of Reproduction, 1995, Vol. 52, pages 331-339) describe the use of an isozyme of lactate dehydrogenase (LDH-C) wherein there was limited results in the fact that there was only a 75% decrease in fertility. The results for O'Hern et al. demonstrate the lack of predictability as to the degree of effectiveness of these techniques. The claimed compounds are disclosed for contraceptive uses, however, according to the prior art, use of sperm surface antigens lacks any reasonable predictability (see

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O'Hern). The product therefore lacks a predictable use for which one of ordinary skill in the art can practice.

4. the amount of direction or guidance presented;

The specification lacks adequate teachings for making all C58 peptides, especially how to use all possible peptides. There is a lack of teaching in the specification as to where the active sites of the C58 peptides are and where and how the claimed modifications would affect the protein-to-protein interactions of the C58 peptides during any contraceptive uses. The claims are to a myriad of peptide sequences that could have similar catalytic activity but have entirely different characteristics as far as protein-protein interactions are concerned. As stated under #3 above, the prior art in this field is unpredictable at best regarding this approach to contraception. Therefore, the claimed compounds lack any teachings as to how to use them.

5. the presence or absence of working examples;

The example in the specification offers no data that can be extrapolated to in vivo contraception. In fact there are no in vivo studies for contraceptive uses of the instantly claimed range of peptides. There are no examples that would lead to a reasonable starting point of extrapolation and analysis of data for in vivo contraception, with contraception being the only specific and substantially claimed use.

6. the quantity of experimentation necessary;

Given the lack of predictability in the prior art, and given the lack of direction, guidance or working examples for use of the claimed compounds for in vivo contraception, there would be an unnecessary experimentation requirement. Especially, since the specification is lacking representative examples of the claimed derivatives of the C58 peptide that have same

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interactions and catalytic and antigenic characteristics for use as contraceptives or for any other use, the experimentation necessary to make and use the plethora of possible peptide sequences instantly claimed.

7. the state of the prior art; and,

Again, the state of the art as represented by O'Hern et al. above is unpredictable regarding the use sperm-specific antigens or peptides for contraception. Although the instant claims are to peptides and compositions thereof, the only substantial and specific uses are for contraception, and there is not enough predictable prior art or guidance in the specification to lead one of ordinary skill in the art to make and use the claimed peptide sequences and compositions thereof.

8. the relative skill of those skilled in the art;

In view of the discussion of each of the preceding seven factors the level of skill in this art is high and is at least that of a Ph.D. or M.D. with several years of experience in the art. As the cited art would point to, even with a level of skill in the art that is highly skilled, predictability of the results is not invariable.

In consideration of each of factors 1 - 8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. (New) Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. As written, claim 20 is not further limiting of the claim 19 because claim 20 recites “an amino acid of SEQ ID NO: 16”. It is indefinite since it is unclear as to whether the claim was intended to recite –an amino acid *sequence* of SEQ IS NO: 16”.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. (Maintained) Rejection of Claims 19-20 and 29 under 35 U.S.C. 102(e) as being anticipated by Edwards et al. (US 2002/0102604 A1) is maintained. Although Applicants have filed an affidavit/declaration under 37 CFR 1.131 to swear behind the applied prior art, the affidavit/declaration must be made by all inventors unless there is a showing that less all inventors were the actual inventors of the claimed subject matter that is rejected as anticipated by the particular prior art reference. Instantly, all pending claims are rejected and there is no showing that all inventors were not the inventors of the rejected subject matter. Therefore, the affidavit/declaration filed under 37 CFR 1.131 is invalid for antedating the rejection. Upon perfection of the affidavit/declaration by the signing of all inventors or a submission showing that not all inventors were inventors of the rejected subject matter, the affidavit/declaration under 37 CFR 1.131 will be considered.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDC


B. DELL CHISM
PATENT EXAMINER